DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 16, 2015

Summit International Medical Technologies, Inc.
Michael Merchant
President
31 Hayward Street, Suite H-1
Franklin, MA 02038

Re: K131950
Trade/Device Name: Angel Tip Safety Intravascular Needle Set
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: FIE
Dated: November 16, 2014
Received: December 18, 2014

Dear Michael Merchant,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -A

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131950

Device Name
Angel Tip Safety Intravascular Needle Set

Indications for Use *(Describe)*
The Angel Tip Safety Intravascular Needle Set is indicated to access the peripheral vascular system for hemodialysis. Additionally, after withdrawal of the needle from the patient's vein, the needle can be manually retracted within a safety enclosure to minimize the risk of an accidental needle stick.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Date Prepared: January 14, 2015

Contact Information: Michael Merchant
President
Summit International Medical Technologies, Inc.
20 Addison Avenue
Franklin, MA 02038 USA
Email: mmerchant@summitmedtech.com
Telephone: (508) 528-3065
Fax: (508) 570-4902

Trade Name:
Angel Tip Safety Intravascular Needle Set

Common Name:
Safety Intravascular Needle Set

Classification Name:
Needle, Fistula: per 21 CFR: 876.5540
Product code: FIE

Predicate Devices

- K912563: Angel Wing Safety Blood Collection and Infusion Set
- K111948: A.V. Fistula Needle Set "WingEater®"

Device Description

The safety needle portion of the Angel Tip Safety Intravascular Needle Set will be available in diameters ranging from 14 to 18 Ga and lengths of 1.0 to 1.5 inches.

The Angel Tip Safety Intravascular Needle Sets are sterile, single use devices designed to access the peripheral vascular system for hemodialysis. Additionally, after withdrawal of the needle from the patient's vein, the needle can be manually retracted within a safety enclosure to minimize the risk of an accidental needle stick. The Angel Tip Safety Intravascular Needle Set consists of a needle attached to a winged hub, microbore or macrobore tubing, adapter and adapter cap and a safety enclosure that attaches to the winged hub.

As the needle is removed from the patient's vessel, the user's finger actively slides the safety enclosure until it latches onto the needle using a one- or two-handed technique. The user will know the needle is engaged based on the tethers being fully extended and

hearing an audible click. The safety enclosure is designed to allow the user's fingers to remain behind the needle point so that the risk of needle stick injury is minimized. The enclosure is clear so the user has a visual means of knowing the needle is captured.

Device Intended Use

The Angel Tip Safety Intravascular Needle Set is indicated to access the peripheral vascular system for hemodialysis. Additionally, after withdrawal of the needle from the patient's vein, the needle can be manually retracted within a safety enclosure to minimize the risk of an accidental needle stick.

Technological Characteristics and Substantial Equivalence

The Angel Tip Safety Intravascular Needle Set is substantially equivalent to the safety enclosure Angel Wing Safety Blood Collection and Infusion Set, cleared under MBO Laboratories, Inc. 510(k) K912563, in terms of design, manufacturing process, functional performance, and materials of construction. The Angel Tip Safety Intravascular Needle Set includes improvements made to the safety mechanism including putting the activation clip on top of the device for easier access, enclosing the clip in the housing to protect it, implementing active engagement to ensure the needle will remain in the housing once it has been retracted and providing both visual (tethers fully extended) and auditory (audible click) indications that the needle is engaged in the housing.

The Angel Tip Safety Intravascular Needle Set is substantially equivalent to the A.V. Fistula Needle Set "WingEater®", cleared under JMS North America Corporation 510(k) K111948, in terms of indications for use and functional performance. There is no change to the fundamental scientific technology of the previously cleared devices or its indications for use as compared to the A.V. Fistula Needle Set "WingEater®".

Nonclinical Testing

The results of the performance testing (tensile, leakage, Luer, corrosion, force to activate and force to override) demonstrate that the Angel Tip Safety Intravascular Needle Set is as safe, as effective and performs comparably to the predicate Angel Wing Safety Blood Collection and Infusion Set and A.V. Fistula Needle Set "WingEater®".

Conclusions

The predicate and the subject devices have similar indications for use, intended use, fundamental scientific technology and similar design, materials, and manufacturing processes. The results of the testing performed have demonstrated that the subject device does not raise new issues of safety or effectiveness and therefore is considered substantially equivalent to the cited predicate devices.